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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,098	04/21/2000	Elena Luriya	101.2	6742

7590 10/10/2002
RASHIDA A. KARMALI, ESQ.
99 WALL STREET
NEW YORK, NY 10005

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/557,098

Applicant(s)
Luriya

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 25, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) 2-4 and 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, and 12-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The change of address dated 5-20-02 and the amendment dated 6-25-02 are acknowledged.

Claims included in the prosecution are 1, 5 and 12-30.

Claim Rejections - 35 USC § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 1, 12-18, 25, 26, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/00824.**

WO discloses liposomal formulations for mucosal application. The formulations contain egg lecithin and antibiotics (note the abstract, Example V and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO teaches away from the invention in that it teaches as an essential element, positively charged vesicle lipid components. This argument is not found to be persuasive since instant claim language does not exclude positively charged

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lipids. Instant claims require egg lecithin as the phospholipid and the reference teaches egg lecithin. The rejection is maintained.

3. Claims 1, 12-20, 22, 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Amselem (5,662,932).

Amselem discloses nanoemulsions containing antifungal agent, miconazole, egg lecithin, tricaprln, cholesterol, oleic acid and tocopherol succinate. The drug:lipid ratios fall within the claimed ratios. The composition further contains surfactants such as Tweens. The modes of administration are oral, rectal and nasal (note the abstract, col. 2, line 33 through col. 3, line 18, columns 5-9 and Example 13 on col. 20).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Amselem teaches lipid core surrounded by at least one phospholipid bilayer and the present invention does not require a phospholipid envelope. This argument is not found to be persuasive since Amselem teaches emulsion formulations and instant claim language does not exclude the envelope in Amselem.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1, 5, and 12-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (6,117,415).

Schwartz discloses oil in water emulsions containing either chlorhexidine or triclosan, egg lecithin, triglyceride, alpha-tocopherol hemisuccinate, Tween, peppermint oil.

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The composition also contains the other claimed surfactants. The particles sizes are 250 nm -350 nm (note the abstract, columns 2-3, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive, Applicant argues that in Schwartz there is a bioadhesive polymer coating. This argument is not found to be persuasive since as pointed out above, instant claim language does not exclude such a coating.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 12-18, 25, 26, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/00824 cited above.

WO does not teach entire claimed range of lipid to active agent. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the active agent amounts from the guidance provided by WO since the amounts of active agents to be administered depends on the condition of the disease and other factors.

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7. **Claims 1, 12-20, 22, 24-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem, (5,662,932) cited above.**

Amselem does not teach entire claimed range of lipid to active agent. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the active agent amounts from the guidance provided by Amselem since as stated above, the amounts of active agents to be administered depends on the condition of the disease and other factors.

8. **Claims 1, 5 and 12-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz (6,117,415) cited above.**

Schwarz does not teach entire claimed range of lipid to active agent. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the active agent amounts from the guidance provided by Schwarz, since as stated above, the amounts of active agents to be administered depends on the condition of the disease and other factors.

Applicant's arguments to the above 103 rejections have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the presence of other components in the references' teachings. These arguments have been addressed above.

9. **THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

The examiner cannot find the PTOL 1449 in the file. Applicant is requested once again to provide a copy of the same.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

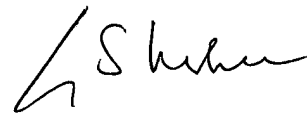
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

A handwritten signature in black ink, appearing to read 'S. Kishore', with a stylized initial 'G' or 'K' to the left.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

October 9, 2002